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(54) BLOOD PUMP CONTROLLER

(71) We, SANDOZ LTD., of 35 Lichtstrasse, CH-4002 Basle, Switzerland, a Swiss Body Corporate, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a blood pump controller. More particularly, the invention is concerned with a controller for an extracorporeal blood pump such as that employed in haemodialysis. Novel apparatus for controlling the blood pump rate in an extracorporeal haemodialysis system is provided.

Many kinds of kidney diseases interfere with the function of the kidney such that the kidney ceases to remove waste and excess water from the blood. When the kidney is sufficiently impaired that a large portion of the waste products and water are not removed from the blood, the life of the patient cannot be preserved unless a way is provided for artificially performing the functions of the impaired kidney through extracorporeal haemodialysis.

Most haemodialysis apparatuses require the use of a blood pump to provide additional pressure in the withdrawn blood in order to conduct it through the haemodialysis unit. A major problem presented by blood pumps and associated control apparatus is the inability of such apparatus to provide a minimum time for dialysis while simultaneously preventing pump starvation and the resulting collapse of the supply blood lines. Blood should be withdrawn from the patient at a rapid rate so as to reduce the time for dialysis. However, when the blood supply at the patient is insufficient to supply the blood pump, the blood lines and even the patient's blood vessels collapse which interrupts effective haemodialysis until adequate blood flow is restored. The collapse of blood lines resulting from insufficient blood supply to a continuously operating blood pump is defined herein as "pump starvation". To avoid time consuming and sometimes dangerous pump starvation, it has been necessary to adjust the pump speed well below an optimum rate to a level which provides a wide safety margin in order to avoid pump starvation. Even with this precaution, however, it is common for the patient's blood flow rate to fluctuate significantly during the course of dialysis. Accordingly, the attending physician must choose between (a) lowering the pump rate to accommodate the lowest possible blood flow rate as a safety margin and thereby significantly extending the dialysis time or (b) risk collapse of blood lines and premature interruption of dialysis through pump starvation in the event of a drop in the patient's blood flow rate.

Attempts have been made to produce a pump which is able to compensate for changes in the amount of available blood while the patient is undergoing dialysis. One attempt involves the use of step-wise regulation apparatus which only varies the volume of blood pumped in a series of discrete steps and does not allow for continuously variable changes in the volume of blood pumped. Such type of pump and control apparatus requires a threshold level of pressure change before any responsive action is taken.

Another type of control apparatus employs specially designed pumps which are mechanically capable of increasing the force applied to a collapsible blood reservoir in order to thereby increase the pressure of blood supplied from the reservoir.

A major deficiency which is observed in attempts to solve the regulation of pump starvation is that the solution involves the replacement of all existing pump controllers and/or blood pumps. Until the advent of the present invention, it has not been possible to continuously vary the rate of a continuous flow blood pump in response to the availability of blood while retaining the existing conventional blood pump and controller for controlling the pump speed.

The present invention provides novel apparatus for continuously varying the pump rate of a blood pump employed in haemodialysis in response to changes in blood flow from the patient so as to maximize the rate of haemodialysis while avoiding pump starvation. Furthermore, the invention provides apparatus which can accomplish the previously described function in combination with existing conventional blood pumps and control mechanisms for ensuring that the pump speed does not rise beyond a predetermined maximum.

In accordance with the invention, there is provided a blood pump controller responsive to changes in blood pressure, which controller includes coupling means for electrical connection respectively to a blood pump for displacing blood through an extracorporeal haemodialysis system and to an electrical power source for driving the pump, and electrical power variation means capable of being electrically interposed between the electrical power source and the blood pump, which electrical power variation means is capable of selectively and continuously varying the amount of electrical power delivered to the blood pump from the said electrical power source in dependence of the change in blood pressure upstream from the blood pump.

More particularly, in accordance with the invention, there is provided a control assembly for controlling the displacement of blood through an extracorporeal haemodialysis system, which control assembly includes a blood pump disposed in a blood-conducting conduit and a blood pump controller, which blood pump controller includes coupling means for electrically connected respectively to the blood pump and to an electrical power source for driving the pump, and electrical power variation means electrically interposed between the power source and the blood pump which electrical power variation means are capable of selectively and continuously varying the amount of electrical power delivered to the blood pump by the power source in dependence of the extracorporeal blood pressure in the blood conduit upstream from the blood pump during the course of dialysis. The coupling means may be located at an attachment site and may enable detachment of the blood pump from the electrical power supply source at the said site.

The electrical power variation means may comprise transducer means for connection to a blood conduit for conducting blood from a patient to the blood pump, which transducer means is capable of producing an electrical control signal representing the availability of blood to the pump, a comparator capable of comparing the transducer signal with a pre-established reference signal and producing an output wave signal of an amplitude dependent upon the said control and reference signals, and switching means for controlling the speed of the blood pump, which switching means is responsive to the output wave signal of the comparator and is capable of producing a periodic pulse train in which the duration of each pulse is proportional to the said amplitude of the output wave signal of the comparator, the speed of the blood pump thereby being a direct function of the duration of the pulse.

The transducer means may comprise averaging means for averaging the systolic and diastolic blood pressures.

The blood pump controller of the invention may further include sensing means, to which the transducer is responsive, for sensing negative blood pressure upstream from the pump, the switching means comprising means capable of producing (a) a medium duration pulse when the proportional output wave signal is at an initial reference level representing a predetermined negative blood pressure, (b) a decreased pulse duration when the proportional output signal indicates reduced patient's blood flow represented by increased negative value of the blood pressure, and (c) an increased pulse duration when the proportional output signal indicates increased patient's blood flow represented by decreased negative value of the blood pressure, the said decreased and increased pulse durations being respectively proportional to the said increased and decreased negative values of the blood pressure. The switching means may further comprise means for keeping open the circuit between the controller and its corresponding power supply for the duration of each pulse.

The comparator described above may comprise an operational amplifier.

The blood pump controller of the invention may further comprise terminating means for terminating the operation of the blood pump when blood flow is reduced below a predetermined level.

The invention will now be described with reference to the accompanying drawings illustrating, by way of example, an embodiment of the invention.

In the drawings:—

Figure 1 is a block diagram illustrating a presently preferred embodiment of the invention;

Figure 2 illustrates a waveform taken at point A in Figure 1, the waveform particularly showing a signal representation when the patient's blood flow has increased during the course of dialysis; and

Figure 3 illustrates a waveform taken at point A of Figure 1, the waveform particularly showing a signal repr sentation when the patient's blood flow has decreased during the course of dialysis.

Referring particularly to Figure 1, an improved controller for a blood pump generally designated 20 is illustrated within the broken line. One of the features of the controller of the invention is that it can be used with existing blood pumps and associated conventional pump controllers such as 39. Accordingly, for ease of illustration, the control assembly for controlling the displacement of blood through an extracorporeal haemodialysis system, which control assembly includes controller 20 and the pump power supply 35, conventional pump controller 39 and blood pump 37 have been schematically illustrated in Figure 1. However, the controller embodying the invention is controller 20 alone.

Blood is continuously forced from the patient to the dialyzer by blood pump 37. Accordingly, the negative pressure will exist in blood lines upstream from the pump. If outflow of the patient's blood should be limited through stricture, clotting, hypotension or any other of a variety of common circumstances, negative pressure upstream from the pump will increase proportionately. Conversely, negative pressure will decrease as blood becomes more available to the pump.

According to one presently preferred embodiment of the invention, a conventional pressure transducer 22 provides a direct conversion between negative pressure in the blood line 24 and electrical voltage. Blood line 24 connects the pressure transducer to a conduit (not shown) which carries blood from a blood vessel of a patient to the blood pump 37. The electrical qualities of the pressure transducer may be characterized as either a variable resistance or a variable voltage source. Whichever type of transducer is employed or whichever electrical characterization is used, the electrical quantity varies in proportion to the blood flow as measured by the negative blood pressure in line 24. The negative pressure is preferably observable on a conventional readout device 23.

The electrical output signal of the pressure transducer is fed into an averaging circuit 28. The averaging circuit 28 may be any one of a wide variety of known discrete or integrated circuits, the most simplified of which would merely be a capacitor in parallel with the transducer output conductors to accomplish averaging of the systolic and diastolic pressure signal from the transducer 22.

Certain types of pressure transducers which maintain a reservoir of blood and mechanically measure expansion and contraction of a chamber would not require the averaging circuit since the output signal from that type of transducer would be averaged mechanically.

The averaged transducer signal is then conducted to one of the inputs to a conventional operational amplifier 31 which forms part of the circuit of a comparator 30. The initial reference control 32 provides a reference signal which is conducted to another of the inputs of the operational amplifier 31. The initial reference control may be either a fixed or variable voltage divider which provides a pre-established signal level.

The operational amplifier 31 used in the circuit of the comparator 30 is used in the summing mode, where the two inputs are added together to form an output to an electronic switch 36 proportional to the sum of the inputs. The electronic switch 36 preferably comprises a conventional threshold trigger circuit capable of converting the output signal of the operational amplifier 31 into a pulse of a duration proportional to the amplitude of the output signal of the operational amplifier. A common, readily available device for performing the function of the electronic switch would be any suitable type of current controlled current source such as a unijunction transistor with an external base to emitter timing capacitance which acts to fire a triac or the like.

The power supply for the operational, amplifier 31 is a pulse generator 34 which produces a generally squarewave voltage signal causing the output of the operational amplifier to turn on and off at a constant rate. Any suitable conventional pulse generator having sufficient voltage output to drive the operational amplifier would be acceptable.

It should be recognized that the signal from the operational amplifier is a periodic pulse having an amplitude proportional to the sum total of the initial reference signal and the averaged transducer signal. The higher the output signal from the comparator, the greater the time increment that switch 36 is on, and conversely the lower the signal from the comparator, the shorter the time increment that switch 36 is on.

The switch may be set so as to be on for a predetermined time interval in response to a predetermined total output signal. Should the total output signal rise above the predetermined value, then the switch remains on for a correspondingly longer time interval, and conversely, should the total output signal fall below the

predetermined value, then the switch remains on for a correspondingly shorter time interval.

As shown in Figure 1, the regular power supply line to a conventional blood pump and controller is diverted through the electronic switch 36. The waveforms shown in Figures 2 and 3 are taken at point A in the diagram of Figure 1, assuming an alternating current power supply like that available at a standard utility outlet. The solid portions of the waveforms represent that portion of the waveforms during which the electronic switch 36 is off. When the switch 36 turns on, it remains on until the AC cycle goes through zero. Because the switch 36 is open or off through most of the AC cycle in Figure 3, the energy delivered from the pump power supply 35 to the pump controller 39 is comparatively small. Thus, the blood pump 37 operates slowly. Conversely, when the switch 36 is on through most of the AC cycle (see Figure 2), the energy delivered to the controller 39 is comparatively high and the blood pump 37 will operate comparatively rapidly.

The existing blood pump controller remains useful for the purpose of setting an upper limit to the speed of the blood pump. However, the invention provides for immediate and continuous compensation of the speed of the blood pump in response to changes in the patient's blood flow. When blood flow decreases, the output of the comparator 30 is reduced and therefore the electronic switch 36 allows a smaller proportion of the pump power supply signal to be conducted to the blood pump (see Figure 3). Also, if the blood flow of the patient should increase during the course of dialysis, the amount of power supplied to the blood pump increases thereby increasing the speed of the pump (see Figure 2). Accordingly, pump starvation caused by a vacuum-induced collapse of blood lines and blood vessels will be avoided because the pump 37 will operate only at the maximum rate accommodated by the available blood supply.

In using the invention, the patient is connected to the dialyzer by conventional method, the supply line 24 being normally in direct communication with the dialyzer blood circuit upstream from the pump. In one preferred method of using a control assembly embodying the invention, the controller 20 is first switched out so as to have no effect on power delivered from the supply 35 to the conventional pump controller 39. Alternatively, the auxiliary controller 20 may remain on but the initial reference control 32 adjusted to the maximum so as not to interfere with the selection of the desirable maximum flow rate at the conventional controller 39.

Subsequently, the blood pump 37 is energized and the speed of the blood pump is increased by adjusting the conventional pump controller 39 to the desired maximum blood flow consistent with a given predetermined negative pressure readout. The desired maximum blood flow may be ascertained by observing the negative pressure read-out 23 and increasing the speed of the blood pump until the negative pressure reaches a level prescribed by the attending physician. Alternatively, the maximum desired flow can be obtained by increasing the pump speed until the blood line or associated accumulator collapses and then reducing the speed of the blood pump 37 through the conventional controller 39 slightly until full flow results.

Once the maximum desired flow has been established in the blood pump 37, the auxiliary controller 20 is activated by adjusting the initial reference control 32 at least until it appears from the negative pressure read-out 23 that the auxiliary controller 20 is monitoring blood flow at essentially the maximum desired rate set by the conventional pump controller 39. It has been found frequently desirable to set the initial reference control on a specific negative pressure reading representing a desirable blood flow rate.

When the initial reference control has been set, the controller 20 will continuously vary the blood pump speed so as to maintain the negative pressure reading at the preset level. Thus, if the patient's blood flow reduces, the controller 20 will reduce the speed of the blood pump 37 so that the negative pressure reading will not significantly change. Conversely, if the patient's blood flow increases, the controller 20 will increase the speed of the blood pump and prevent the negative pressure level from changing significantly.

The most advantageous physical housing for the invention has been found to be an enclosure (not shown) which provides an electrical outlet for the service plug of the conventional blood pump and controller, a meter for indicating the negative pressure, and a dial plate and dial for setting the initial reference control. Of course, various power switches, pilot lights, or other indicators may be used in order to monitor the status of the circuit operation.

WHAT WE CLAIM IS:—

1. A blood pump controller responsive to changes in blood pressure, which controller includes coupling means for electrical connection respectively to a blood pump for displacing blood through an extracorporeal haemodialysis system and to an electrical power source for driving the pump, and electrical power variation means

capable of being electrically interposed between the electrical power source and the blood pump, which electrical power variation means is capable of selectively and continuously varying the amount of electrical power delivered to the blood pump from the said electrical power source in dependence of the change in blood pressure upstream from the blood pump.

2. A blood pump controller according to claim 1, wherein said electrical power variation means comprises transducer means for connection to a blood conduit for conducting blood from a patient to the blood pump, which transducer means is capable of producing an electrical control signal representing the availability of blood to the pump, a comparator capable of comparing the transducer signal with a pre-established reference signal and producing an output wave signal of an amplitude dependent upon the said control and reference signals, and switching means for controlling the speed of the blood pump, which switching means is responsive to the output wave signal of the comparator, and is capable of producing a periodic pulse train in which the duration of each pulse is proportional to the said amplitude of the output wave signal of the comparator, the speed of the blood pump thereby being a direct function of the duration of the pulse.

3. A blood pump controller according to claim 2, wherein the transducer means comprises averaging means for averaging the systolic and diastolic blood pressures.

4. A blood pump controller according to claim 2 or claim 3 wherein the transducer is capable of sensing negative blood pressure upstream from the pump and wherein the switching means is capable of producing (a) a medium duration pulse when the proportional said output wave signal is at an initial reference level representing a predetermined negative blood pressure, (b) a decreased pulse duration when the said proportional output signal indicates reduced patient's blood flow represented by increased negative value of the blood pressure, and (c) an increased pulse duration when the proportional output signal indicates increased patient's blood flow represented by decreased negative value of the blood pressure, the said decreased and increased pulse durations being respectively proportional to the said increased and decreased negative values of the blood pressure.

5. A blood pump controller according to claim 4, wherein the switching means further includes means for keeping open the circuit between the controller and its corresponding power supply for the duration of each pulse.

6. A blood pump controller according to any one of claims 2 to 5, wherein the comparator comprises an operational amplifier.

7. A blood pump controller according to any one of the preceding claims, which further comprises terminating means for terminating the operation of the blood pump when blood flow rate falls below a predetermined level.

8. A control assembly for controlling the displacement of blood through an extracorporeal haemodialysis system, which control assembly includes a blood pump disposed in a blood-conducting conduit and a blood pump controller, which blood pump controller includes coupling means electrically connected respectively to the blood pump and to an electrical power source for driving the pump, and electrical power variation means electrically interposed between the power source and the blood pump which electrical power variation means are capable of selectively and continuously varying the amount of electrical power delivered to the blood pump by the power source in dependence of the extracorporeal blood pressure in the blood conduit upstream from the blood pump during the course of dialysis.

9. A control assembly according to claim 8 wherein the coupling means is detachably coupled, at an attachment site, to the said power source and the said pump to allow detachment of the pump from the power source.

10. A control assembly according to claim 8 or claim 9 which further includes means for maintaining the speed of the blood pump at a speed below a predetermined value.

11. A blood pump controller responsive to changes in blood flow, substantially as herein described with reference to the accompanying drawings.

12. A control assembly for controlling the displacement of blood through an extracorporeal haemodialysis system, which control assembly is substantially as herein described with reference to the accompanying drawings.

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2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 1

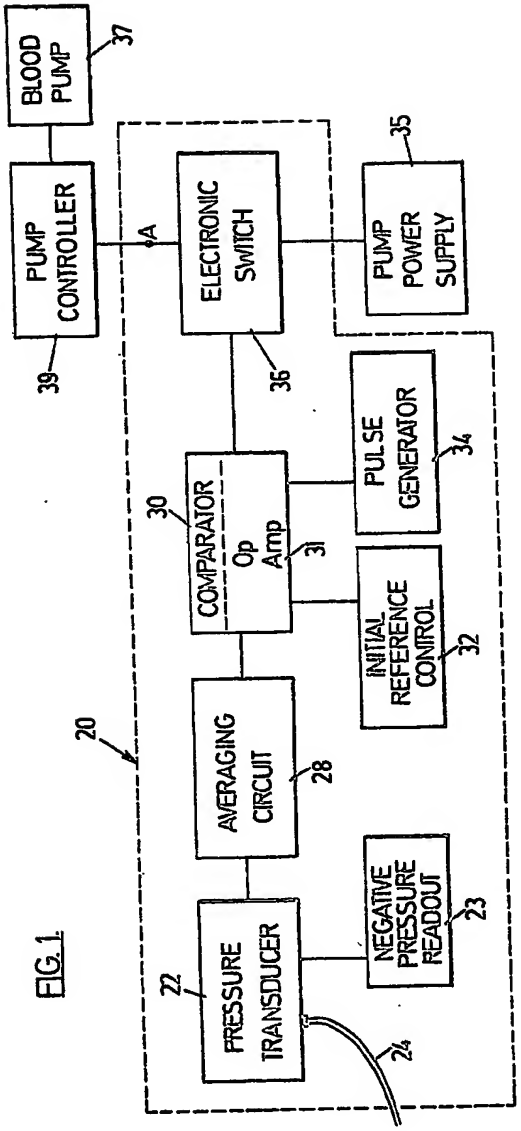

FIG. 1

1487242 COMPLETE SPECIFICATION
2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 2

FIG.2.

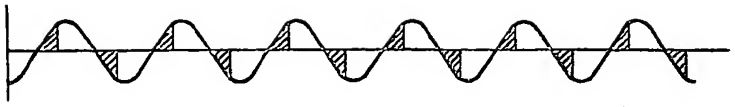

FIG.3.